

**03-1237 MERCK KGAA V. INTEGRA LIFESCIENCES I, LTD., ET AL.**

**DECISION BELOW: 331 F.3d 860 (Fed. Cir. 2003)**

**QUESTION PRESENTED**

To encourage development and expedite introduction of pharmaceuticals, Congress amended the patent laws in 1984 to insulate drug research from charges of infringement so long as the research is "reasonably related to the development and submission of information" to the Food and Drug Administration. Did the Federal Circuit err in concluding that this drug-research safe harbor does not protect animal studies of the sort that are essential to the development of new drugs, where the research will be presented to the FDA, and where barring the research until expiration of the patent could mean years of delay in the availability of life-saving new drugs?

Cert. Granted 1/7/05